

Att'y Dkt. No. US-1350

U.S. App. No: 09/636,458

REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks. The foregoing amendments do not present new matter, and therefore, entry is respectfully requested.

Interview on November 17, 2004

Applicant's representative appreciates the very helpful interview held with the Examiner.

Substitute Specification

Applicants thank the Examiner for indication of entry of the substitute specification.

The rejection of the claims under 35 U.S.C. §112, 1st paragraph (enablement)

The Examiner has rejected claims 9-10, 12-13, 18, 20, and 29 under 35 U.S.C. §112, 1st paragraph since the specification does not allegedly provide enablement for nucleic acids and plasmids comprising sequences at least 90% or at least 99% homologous to SEQ ID NO:4 or a method for isolating a plasmid comprising a sequence encoding a polypeptide having Rep activity and is at least 90% homologous to SEQ ID NO:4. The Examiner alleges that there is no disclosure of the functional motifs essential for activity of Rep proteins, or the regions of Rep proteins essential for activity, or not teaching the skilled artisan how to make the claimed polynucleotides.

Applicants provide herewith a homology map and BlastP sequence search of similar Rep proteins. This homology map shows that there are many conserved regions within the family of Rep proteins and the BlastP search shows the relatedness of similar proteins. Such conservation of related sequences clearly indicates to the skilled artisan that these are regions which should not be altered, since their conservation strongly suggests functional significance. In fact, the region beginning at position 361 through 374 is known to be the region responsible for nicking plasmids (see table 5 of Nesvera et al.). This region is conserved in the claimed plasmid. If one were to only potentially alter the

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non-conserved residues, this amounts to choosing among 171 residues. However, the claims require that the protein be 90% homologous, which only allows for up to 54 amino acids to be altered. Clearly, the skilled artisan, armed with applicant's specification, the knowledge in the art about other Rep proteins, and the high level of skill in the art, would be able to make and identify proteins within 90% homology to SEQ ID NO:4.

Applicants also submit herewith the article by Nesvera et al., which reports sequence homology among other Rep plasmids, as well as identification of regions which convey activity (see table 5). Such structure/function information is clearly sufficient to provide the skilled artisan with sufficient guidance as to 1) providing a level of predictability regarding structural motifs and their relation to function of the encoded protein, 2) providing information on the state of the art regarding structure/function information of Rep proteins, 3) determining proteins within the narrow (54 amino acid possible changes) scope of the claims, 4) a sufficient amount of guidance regarding the correlation between structure and function, 5) the nature of the invention, 6) the high level of skill in the art. An analysis of these factors clearly indicates that applicants have provided sufficient information for the skilled artisan to make and use the claimed invention within the scope of the claims.

For these reasons, applicants respectfully request withdrawal of the rejection.

The rejection of the claims under 35 U.S.C. §112, 1st paragraph (written description)

Claims 9-10, 12-13, 18, 20, and 29 were rejected under 35 U.S.C. §112, 1st paragraph for allegedly failing to comply with the written description requirement. The Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicants contend that although the claims recite a genus of nucleic acid sequences encoding proteins homologous to SEQ ID NO:4 (either 90% or 99%), the specification cannot be read in a vacuum. The state of the art and the knowledge gained by the skilled artisan regarding the state of the art must also be taken into account. Applicants demonstrate by citation of the Nesvera et al. article as well as the attached homology map and BlastP sequence search that there was sufficient knowledge in the art regarding related

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Rep proteins to provide the skilled artisan with a correlation between structure and function sufficient to show possession of the claimed invention. The Examiner contends that applicants recite the claimed nucleic acids by function only, however this is simply incorrect. A structural limitation is present in the claims in that the encoded protein must be at least 90% homologous to SEQ ID NO:4. The Nesvera et al. article points to the functional domain of amino acids 361 to 374 as being responsible for the 'nicking' activity of the protein, and other conserved regions are clearly pointed out on the attached homology chart. One of skill in the art would know not to make changes in these conserved domains, therefore, leaving fewer options for altering the protein sequence. Therefore, applicants have provided sufficient information both in their specification combined with the knowledge in the art to demonstrate possession, and hence sufficient written description, of the claimed invention.

For these reasons, applicants respectfully request withdrawal of the rejection.

The rejection of claim 13 under 35 U.S.C. §112, 2nd paragraph

Claim 13 was rejected under 35 U.S.C. §112, 2nd paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claim 13 as discussed in the interview of November 17, 2004 to remove the alleged ambiguity.

For these reasons, applicants respectfully request withdrawal of the rejection.

The objection to claim 13 under 37 C.F.R. §1.75(c)

Claim 13 was objected to for allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have amended the claim to place it in proper dependent form.

For these reasons, applicants respectfully request withdrawal of the objection.

The objection to the drawings

The drawings were objected to for containing characters of insufficient height. Applicants are currently making the necessary corrections and will submit replacement drawings shortly.

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Conclusion

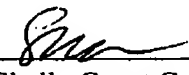
For at least the foregoing reasons, Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If Examiner Guzo believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the undersigned respectfully requests that she be contacted immediately.

Respectfully submitted,

By: _____


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